EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

ABBVIE INC. *et al.*, *Plaintiffs*, v. LIZ MURRILL, in her official capacity as Attorney General of Louisiana, *Defendant*.	**Case No. 6:23-CV-01307** **JUDGE: Robert R. Summerhays** **MAGISTRATE JUDGE: Carol B. Whitehurst**

INTERVENOR-DEFENDANT'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Act 358 is not preempted because it governs drug distribution, and the federal 340B statute governs drug pricing. Identical preemption arguments failed in the Eighth Circuit, which upheld an Arkansas law substantially similar to Act 358. *Pharm. Rsch. & Mfrs. of Am. v. McClain* ("*PhRMA*"), 95 F.4th 1136 (8th Cir. 2024). The 340B statute does not expressly preempt state drug distribution laws. It also does not impliedly preempt those laws because the 340B statute is not a comprehensive regulatory scheme and is silent on drug distribution. Congress acquiesced to state regulation of drug distribution by declining to address contract pharmacy arrangements when amending the 340B statute.

Act 358 is not an unlawful taking under the Takings Clause of the United States Constitution, U.S. Const. amend. V., or the Louisiana Constitution, La. Const. art. I, § 4. Act 358 is not a *per se* taking because Act 358 does not seize 340B drugs and deprive AbbVie of the entire value of its property. Likewise, Act 358 is not a regulatory taking because it does not set prices, does not disturb AbbVie's investment-backed expectations, which have long included shipments to contract pharmacies, and furthers the important public interest of protecting the health of Louisiana residents. Finally, the term "interfere" in Act 358 is not unconstitutionally vague, and a person of ordinary intelligence would understand what Act 358 prohibits.

FACTUAL BACKGROUND

AbbVie presents a distorted and misleading picture of contract pharmacies and the replenishment model used by contract pharmacies and many other entities in the drug distribution supply chain. Most illnesses and injuries cannot be treated or managed adequately without the patient taking one or more medications. That means a provider of health care must ensure that patients have access to a pharmacy to fill their prescriptions. For this reason, many

providers own and operate their own pharmacies, commonly referred to as "in-house pharmacies." In-house pharmacies, however, are expensive to establish, particularly for small providers, and fall short of meeting the pharmacy needs of all patients, so many providers enter into contract pharmacy arrangements with community pharmacies.

Most drugs are not sent directly from manufacturers to pharmacies. *See* Dep't of Health & Hum. Servs., Off. of Inspector Gen., OEI-05-14-00640, *Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, at 4 (2019)[1]; Kaiser Family Foundation, *Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* 3-4, 8-10 (2005) ("*Follow the Pill*").[2] Rather, pharmacies contract with wholesalers that purchase the manufacturer's drugs. *Follow the Pill* at 10. A pharmacy or health care provider then purchases drugs from the third-party wholesaler. *Id.* at 10, 18. If the pharmacy or health care provider is entitled to a discount from the manufacturer, the initial transaction with the wholesaler is at wholesale acquisition cost ("WAC"), and the wholesaler subsequently initiates a reconciliation, known as a "charge back." *Id.* at 19.

Because the construction and management of a pharmacy is expensive and requires special expertise, many 340B covered entities, including the Louisiana Primary Care Association's ("LPCA's") members, cannot afford to "expend precious resources to develop their own in-house pharmacies." Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) ("1996 Guidance"). They rely instead on independent retail pharmacies to dispense drugs on their behalf. Providers with large service areas also contract with independent pharmacies that are

[1] https://oig.hhs.gov/oei/reports/oei-05-14-00640.pdf.
[2] https://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf.

accessible where the provider's patients reside. Some medications require special storage and handling and can only be dispensed by a specialty pharmacy,[3] through a mail order program, or through a limited distribution network.[4] These contract pharmacy arrangements have long been blessed by the federal Department of Health and Human Services ("HHS"), which administers the 340B program. 1996 Guidance, 61 Fed. Reg. at 43549; Notice Regarding 340B Drug Pricing Programž Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010) ("2010 Guidance").

Contrary to AbbVie's assertion, Pls.' Opp'n 4 n.2, 20, 21, ECF No. 70, covered entities retain title to 340B drugs shipped to contract pharmacies. Contract pharmacies are not permitted to purchase 340B drugs. 2010 Guidance, 75 Fed. Reg. at 10277. Wholesalers do not establish 340B purchasing accounts for contract pharmacies because contract pharmacies are not eligible for these discounts. A covered entity establishes a 340B account with the wholesaler, enabling the covered entity to purchase 340B-discounted drugs. The wholesaler creates a "ship to, bill to" arrangement in which the 340B drugs are billed to the covered entity and shipped to the contract pharmacy. *Id.* A covered entity must "purchase the drug, maintain title to the drug and assume responsibility for establishing its price…." *Id.* The contract pharmacy dispenses the drugs to the covered entity's patients, collects reimbursement for the drugs from both the patient and the patient's third-party payer (if any), and remits the collected reimbursement to the covered entity. The covered entity, in turn, pays the pharmacy a fee for providing the service of dispensing and billing 340B drugs on the covered entity's behalf.

Contract pharmacy arrangements are built on the well-established commercial practice of

[3] *See Specialty Pharmacies*, Am. Pharmacists Ass'n, https://www.pharmacist.com/Practice/Patient-Care-Services/Specialty.

[4] "Under a limited distribution network, a manufacturer contracts with one or a few specialty pharmacies to dispense high-maintenance medications." *Limited Distribution Drugs 101*, Clarivate (Sept. 27, 2019), https://clarivate.com/blog/limited-distribution-drugs-101/.

one party purchasing and taking title to a product and a second party taking possession of the product on the first party's behalf. Contract pharmacy distribution arrangements are commonly used within the U.S. drug distribution system and are not unique to the 340B Program. *See, e.g.*, F.T.C., Univ. of Mich. Advisory Op'n Letter to Dykema Gossett (Apr. 9, 2010)[5]; 134 Cong. Rec. H6971-02 (1988) (statement of Rep. Charlie Rose) ("[H]ealth centers often include onsite pharmacies, or agreements with community pharmacists to ensure that the medicines needed to treat or control these chronic conditions are available."); *Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and Means*, 91st Cong. 2129 (1969) (statement of Jacob W. Miller, Chairman, Comm. Pub. Affs., Am. Pharm. Ass'n) ("As I am sure you are aware, many health care facilities do not maintain their own onsite pharmaceutical services … [r]ather, they look to the community pharmacies to provide such service on a contract basis.").

Replenishment inventory systems are commonplace. When a manufacturer sells drugs through a wholesaler, the drugs shipped to the wholesaler are not intended to fill a particular order placed by a pharmacy; instead, they supply inventory to the wholesaler that the wholesaler then sells to a pharmacy. *See, e.g.*, Robert Handfield, Biopharmaceutical Supply Chains 11-13 (2012) (ebook). Even if the drugs shipped by the manufacturer to the wholesaler filled an order placed by a pharmacy, the drugs would not necessarily be the same drugs delivered by the wholesaler to the pharmacy because prescription drugs are manufactured in a precise and reproducible manner that make them fungible. *See* 21 U.S.C. §§ 360(e), 360eee-1; 21 C.F.R. § 207.33. The fungibility of prescription drugs enables wholesalers and manufacturers to use a replenishment-based system for distributing drugs under which the wholesaler purchases a large stock of drugs and replenishes that stock with additional purchases from the manufacturer as the

[5] https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf.

wholesaler's inventory declines. *See* Handfield at 11-13, 24-31.

Covered entities and contract pharmacies rely on the same replenishment-based inventory management process used by wholesalers and manufacturers. The pharmacy loans its initial inventory to the covered entity to dispense to the covered entity's patients, and the covered entity then replaces 340B drugs for those *already dispensed* by the pharmacy as replacement for (or replenishment of) the starting inventory. Brief of Appellee Cmty. Health Ctrs. of Ark. and Piggott Cmty. Hosp., Decl. of Krista M. Pedley, ¶¶ 7-9, *PhRMA*, 95 F.4th 1136 (8th Cir. 2024) (No. 22-3675) ("Pedley Decl."). To ensure that the replenishment process is implemented compliantly, covered entities and pharmacies use software to track drugs dispensed to the covered entity's patients and then place replenishment orders based on those dispensations. *Id.* at 5-9, 12; *see also* 1996 Guidance, 61 Fed. Reg. at 43554 ("[T]he requirement for a separate inventory of 340B drugs is unnecessary, because the covered entity is required to monitor dispensing and inventory records" and those "records will accurately indicate use of 340B drugs"). By ensuring that 340B replenishment drugs are only purchased if they replace drugs that have been dispensed to the covered entity's patients, covered entities always retain title to 340B drugs that are dispensed to their patients. *Cf.*, *United States v. Gen. Elec. Co.*, 272 U.S. 476, 484 (1926) (a distribution partner of General Electric did not take title to the fungible goods, but "title passes directly from [General Electric] to [General Electric's end] purchasers").

ARGUMENT

I. Act 358 Is Not Preempted

Act 358 is neither field preempted nor conflict preempted. Congress has not occupied the entire field of drug distribution. *PhRMA*, 95 F.4th at 1143. Act 358 is also not subject to conflict preemption because Act 358 and the 340B statute act in separate spheres—section 340B determines drug pricing, while Act 358 governs intra-state distribution of drugs that have already

been priced under section 340B.

A. Act 358 Does Not Intrude on an Exclusively Federal Field of Operation, Nor Does It Conflict With Congress's Objectives

1. Act 358 is Not Field Preempted

AbbVie is incorrect that Act 358 is field preempted. First, Congress has not established a regulatory framework for 340B that is "so pervasive" that it "left no room for the States to supplement it." *PhRMA*, 95 F.4th at 1143 (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)). Second, there is no dominant federal interest so strong that it can "be assumed to preclude enforcement of state laws on the same subject." *Id.*

AbbVie relies heavily on *Arizona v. United States* for the proposition that "[field] preemption bars any attempt to upset the balance Congress struck" for 340B. Pls. Opp'n 6-7, ECF No. 70. This case does not support AbbVie's position. First, *Arizona* dealt with subject matter in which the federal government has "broad, undoubted power": immigration and the status of foreign nationals. *Arizona*, 567 U.S. at 394. Governance of immigration policy is "well settled," "fundamental," "extensive and complex," and "one of the most important and delicate" powers the federal government holds. *Id.* at 395. Unlike immigration policy, Congress has not occupied the field of 340B drug distribution. HHS and several federal courts have confirmed that the 340B statute is not a comprehensive and exclusive scheme and is silent about drug delivery and distribution. *See e.g.*, *PhRMA*, 95 F.4th at 1143 ("[T]he text of 340B is silent about delivery of drugs to patients." (quotations omitted)); 1996 Guidance, 61 Fed. Reg. at 43549 ("The [340B] statute is silent as to permissible drug distribution systems."). Second, *Arizona* dealt with state penalties for the exact conduct regulated under federal law. *Arizona*, 567 U.S. at 401. The 340B statute and Act 358 regulate different conduct, pricing and distribution.

Contrary to AbbVie's assertion, federal courts have upheld state laws "in the context of a

federal law as comprehensive" as 340B. Pls.' Opp'n 10-11 n.3. In *New York State Dep't of Social Services v. Dublino*, the Supreme Court held that a state statute that imposed employment requirements as conditions for continued eligibility for Aid to Family with Dependent Children ("AFDC") was not preempted even though the state requirements were more onerous than the federal AFDC work requirements. *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973). The federal AFDC was "comprehensive" and "complex," yet the court noted that the "subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem."[6] *Id.* at 415.

2. Act 358 Is Not Conflict Preempted

Act 358 neither disrupts the balance nor frustrates the objectives that Congress created for the 340B program, as AbbVie's argues. Pls.' Opp'n 9. Rather, "it does the opposite: Act [358] assists in fulfilling the purpose of 340B." *PhRMA*, 95 F.4th at 1144-45. Congress has not provided clear evidence that it intended the federal government to have exclusive authority to oversee all aspects of the 340B program. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Congress has traditionally left the regulation of drug distribution to the states, LCPA Br. 1, 14, 19, ECF No. 61-1, and the 340B statute gives no indication that Congress intended to confer authority on the federal government to regulate drug distribution exclusively. The conduct that Act 358 seeks to regulate is not dictated by the 340B statute. *See PhRMA*, 95 F.4th at 1144-45 (holding that a law similar to Act 358 "does not set or enforce discount pricing" and that its "penalties are aimed at activity that falls outside the purview of 340B.").

Act 358 does not add requirements to the 340B program because it "does not require

[6] Even if the 340B statute were comprehensive—and it is not—the Court has rejected the "contention that pre-emption is to be inferred merely from the comprehensive character [of a federal law]." *Dublino*, 413 U.S. at 415.

manufacturers to provide 340B pricing discounts to contract pharmacies." *Id.* As LPCA explained in its opening brief at 11-12, Congress was aware that health care providers use contract pharmacies when it enacted the 340B statute, and, when it amended the statute in 2010, it was also aware of HHS's longstanding policy to permit contract pharmacies and its related interpretation that the 340B "statute is silent as to permissible drug distribution systems." 1996 Guidance, 61 Fed. Reg. at 43549.

Contrary to AbbVie's assertions, the "logic of *Astra*" is not controlling, and, importantly, *Astra* is not a preemption case, which AbbVie concedes. Pls.' Opp'n 10. AbbVie places significant weight on *Astra* to support its preemption arguments and claims that it is "irrelevant" that *Astra* is not a preemption case. Pls.' Opp'n 10-11. *Astra* only addresses pricing matters expressly governed by the 340B statute, which are overcharge complaints by covered entities, and does not address a state's regulation of drug distribution within its borders. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011) ("[T]he County based its suit on allegations that the manufacturers charged more than the § 340B ceiling price …."). AbbVie inconsistently argues that the State cannot rely on *Evans v. Loveland Auto. Invs., Inc.*, 632 F. App'x 496 (10th Cir. 2015) because "*Evans* is not a preemption case." *Id.* at 10-11 n.3. By AbbVie's own reasoning, its reliance on *Astra* is also "especially misplaced." *Id.*

B. AbbVie Has Not Countered LPCA's Arguments

1. Act 358 Regulates Delivery, Not Price

Act 358 functions as a delivery statute, despite AbbVie's contrary mischaracterization. Pls.' Opp'n 11. As AbbVie states, a "proper [preemption] analysis requires consideration of what the state law in fact does, not how the litigant might choose to describe it." Pls.' Opp'n 14; *see Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 637 (2013). Act 358 in fact does not regulate the price of 340B drugs. *See PhRMA*, 95 F.4th at 1145 (Arkansas "Act 1103 does not require

manufacturers to provide 340B pricing discounts to contract pharmacies. Act 1103 does not set or enforce discount pricing."). Pricing of 340B drugs is established pursuant to the 340B statute and before the requirements of Act 358, which addresses drug distribution, comes into play. To state the obvious, covered entities purchase drugs at 340B prices before they are delivered.

AbbVie maintains that the Attorney General is bound by certain alleged "admissions." Pls.' Opp'n 11-12. Even if the Attorney General is bound by these statements (which LPCA does not concede), LPCA cannot be bound by the Attorney General's statements in her responsive pleading. Such statements, at most, are only binding on the party that made them and are not binding on a co-party, such as LPCA. *Becerra v. Asher*, 105 F.3d 1042, 1048 (5th Cir. 1997) ("Deemed admissions by a party opponent cannot be used against a co-party."); *State Farm Mut. Auto. Ins. Co. v. Dyer*, 19 F.3d 514, 519 n.9 (10th Cir. 1994); *Riberglass, Inc. v. Techni-Glass Indus., Inc.*, 811 F.2d 565, 566-67 (11th Cir. 1987); 32 C.J.S. Evidence § 552 ("an admission of one party is not binding on, or evidence against, a coparty[.]").

AbbVie's hypothetical regarding temperature-controlled trucks, Pls.' Opp'n 12, ignores that state law is "a complementary form of drug regulation" that "offers an additional, and important, layer of consumer protection." *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009). While Act 358 may appropriately complement the federal 340B statute, pricing and distribution are not "inextricably linked" as AbbVie argues. Pls.' Opp'n 13. Thus, Act 358 does not effect a private wealth transfer of AbbVie's property for a public benefit, nor will it have that effect. Pls.' Opp'n 14-15. Congress established the 340B pricing formula, not Louisiana, and AbbVie voluntarily chose to participate in the 340B program.

Act 358 also does not divert the benefits from the 340B program away from covered entities and patients and to contract pharmacies, as AbbVie argues. Pls.' Opp'n 12-14. Of

course, a covered entity compensates the pharmacy for its work providing dispensing services. A covered entity's payment of a dispensing fee for contract pharmacy services does not mean that the contract pharmacy participates in the 340B program or that it realizes any benefit other than compensation for its services to the covered entity.

AbbVie is also incorrect that contract pharmacy arrangements have driven the growth of the 340B program since 2010. Pls.' Opp'n 15. Rather, 340B has grown because Congress expanded the program in 2010. Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, § 7101-03, 124 Stat. 119, 821-28 (2010). In the ACA, Congress added five categories of hospitals as covered entities. *Id.* § 7101(a), 124 Stat. 821-822; 42 U.S.C. § 256b(a)(4)(M)-(O). Any growth is due principally to Congress's enlarging the program.

Further, Act 358 does not add contract pharmacies onto the specifically enumerated list of covered entities. *See* Pls.' Opp'n 9; 42 U.S.C. § 256b(a)(4). Rather, contract pharmacies function as a necessary mechanism to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12. Act 358, which regulates the distribution of 340B priced drugs purchased by the statutory fifteen covered entity types, is not the same as a state law requiring manufacturers to treat contract pharmacies as a sixteenth type of covered entity.

The 340B statute governs the pricing of drugs and to whom 340B drugs may be sold and resold but is silent on contract pharmacies and how 340B drugs travel from manufacturer to patient. 42 U.S.C. § 256b(a)(1), (a)(4), (a)(5)(B). AbbVie's contract pharmacy policy demonstrates that pricing and distribution are distinct: "AbbVie declines to facilitate bill to/ ship to orders for all hospital covered entities for 340B-priced medicines. . . . Accordingly, hospital covered entities are not permitted to direct delivery of AbbVie's 340B priced medicines to

contract pharmacies." AbbVie Policy, 340B ESP, https://www.340besp.com/resources. AbbVie acknowledges that 340B prices are established before distribution. After the 340B price is set, AbbVie refuses "to direct delivery of AbbVie's 340B priced medicines to contract pharmacies."

AbbVie argues that 340B regulates both price and delivery, citing the statute's references to a prime vendor, Pls.' Opp'n 15, but the Third Circuit interpreted those references completely differently, noting that Congress's creation of the optional prime vendor program demonstrates that the statute is otherwise silent about how 340B drugs travel from manufacturer to covered entities. *Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 704 (3d Cir. 2023) ("Congress also knew how to impose delivery-related requirements" in 340B because it created a prime vendor program obligating manufacturers to 'be responsible for the costs of distribution' while not regulating distribution more generally." (quoting 42 U.S.C. § 256b(a)(8)). Congress was fully aware when it enacted the 340B statute that health care providers used contract pharmacies to distribute drugs to their patients, *Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566 at *2 (S.D. Ind. Oct. 29, 2021), and chose to remain silent regarding distribution.

Congress's limitation of 340B pricing to covered entities, which may only dispense the drugs to their patients, does not constitute a distribution restriction as AbbVie contends. Pls.' Opp'n 16. Covered entities and patients are the intended beneficiaries of the statute. Act 358 addresses distribution from manufacturers to these intended beneficiaries.

2. Act 358 Is Entitled to the Presumption Against Preemption; Congress Knew How to Preempt State Health Laws and Chose Not to Do So

The cases cited by AbbVie to support its preemption argument are distinguishable and do not preclude the application of the presumption against preemption here. *Buckman*, 531 U.S. at 347-48 (contemplating policing fraud against federal agencies: "hardly a field which States have

traditionally occupied." (quotations omitted)); *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504-05 (1988) (state law invoked "obligations to and rights of the United States under its contracts" and "civil liability of federal officials for actions taken in the course of their duty," which were widely found to be "governed exclusively by federal law."); *Forest Park II v. Hadley*, 336 F.3d 724, 731-32 (8th Cir. 2003) (statute contained an express preemption provision and "regulate[d] or restrict[d] the actions of the federal government under its own federal program."). Despite AbbVie's assertions, the long-standing presumption against federal preemption of state law is fully applicable here. Pls.' Opp'n 16-18. The Eighth Circuit recently applied the presumption against preemption to an Arkansas law similar to Act 358. *PhRMA*, 95 F.4th at 1140.

Under the presumption against preemption, courts assume that federal law does not supersede the historic police powers of states unless Congress expresses a "'clear and manifest'" purpose to do so. *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715 (1985) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)); *see also Wyeth*, 555 U.S. at 565. As LPCA has repeatedly explained, Act 358 governs distribution of drugs that have already been priced. Congress has expressed no such clear and manifest purpose under the 340B statute to displace states' historic powers to regulate drug distribution.

AbbVie argues that Act 358 does not address areas that are traditionally regulated by state law. Pls.' Opp'n 17-18. But AbbVie's restrictions on distributing 340B drugs to local Louisiana pharmacies harm the health of Louisiana's citizens by depriving them of access to affordable medications, which Act 358 seeks to remedy. Courts have long recognized a state's interest in regulating areas of public health. *See, e.g.*, *Hillsborough Cnty.*, 471 U.S. at 719 ("[R]egulation of health and safety matters is primarily, and historically, a matter of local concern."). This Court should not, therefore, "conclude that Congress legislated the ouster of [a] [State]

statute . . . in the absence of an unambiguous congressional mandate to that effect."[7] *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 146–47 (1963).

Contrary to AbbVie's unsupported assertions, LPCA has demonstrated that Congress acquiesced to states' authority to oversee drug distribution arrangements. Pls.' Opp'n 18-19. AbbVie cites no case law and merely offers conclusory statements such as "Act 358 is not a state health law" and "proper inference from congressional silence about state regulation in the 340B sphere is that Congress did not intend to allow it at all." *Id.* AbbVie is wrong on both counts. The Eighth Circuit recently found that "[p]harmacy has traditionally been regulated at the state level" and that an Arkansas state law similar to Act 358 "impact[s] health and welfare." *PhRMA*, 95 F.4th at 1144 (citing *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)).

Congress is presumed to be "knowledgeable about existing law pertinent to the legislation it enacts." *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 184 (1988). In fact, "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 940-41 (8th Cir. 2011) (quotations omitted). Congress has considered several proposed bills that would address contract pharmacy arrangements, demonstrating its awareness of these arrangements. Healthy America Act of 2005, S. 4, 109th Cong. § 332(b) (2005); 340B Program Improvement and Integrity Act of 2007, S. 1376, 110th Cong. § 5(a) (2007). Additionally, Congress expansively modified the 340B statute in the ACA,

[7] AbbVie's hypothetical about subsidized produce and wealthy individuals misses the mark. Pls.' Opp'n 18 n.7. The 340B statute requires that covered entities provide 340B drugs only to their patients. 42 U.S.C. § 256b(5)(B), (D)(d)(2). The type of diversion AbbVie describes is expressly prohibited by the 340B statute, therefore, and covered entities are not selling 340B drugs to pharmacies, as AbbVie's hypothetical implies. A more apt hypothetical would involve a state law protecting contracts between homeless shelters and grocery stores in low-income neighborhoods to distribute discounted food to the shelters' clients on behalf of the shelters. Such a state law would be entitled to the presumption against preemption. *Hillsborough*, 471 U.S. at 715.

adding several categories of covered entities and program integrity measures, while remaining silent on drug distribution and contract pharmacies.[8] ACA, Pub. L. No. 111–148, § 7101, 124 Stat. 821. Here, "[t]he proper inference from congressional silence," Pls.' Opp'n 19, is the one the Eighth Circuit noted: "Congress was aware of the role of pharmacies and state pharmacy law in implementing 340B" and its "silence on pharmacies in the context of 340B indicates that Congress did not intend to preempt the field." *PhRMA*, 95 F.4th at 1144.

C. The Eighth Circuit's Decision in *PhRMA v. McClain* is Applicable and Persuasive

As AbbVie noted, "the Eighth Circuit recently rejected a preemption challenge to an Arkansas law requiring pharmaceutical manufacturers to provide their drugs to pharmacies that contract with a covered entity." Pls.' Opp'n 19 (discussing *PhRMA*, 95 F.4th at 1143). AbbVie argues that Act 358 is distinguishable from Arkansas Act 1103, and this Court should disregard *PhRMA*. The only meaningful distinction between Act 1103 and Act 358 supports LPCA's position because Act 358 expressly requires consistency with federal law: "Nothing in this Chapter is to be construed or applied to be in conflict with any of the following: (1) Applicable federal law and related regulations…." La. Stat. Ann. § 40:2886. HHS requires that contract pharmacies act as agents of covered entities and that covered entities maintain title to drugs shipped to contract pharmacies. 2010 Guidance, 75 Fed. Reg. at 10277. Act 358 is even more clearly not preempted than Act 1103. *PhRMA* is thus on point and persuasive.

In the same way that Act 1103 regulates delivery of 340B drugs, so does Act 358. Act 358 states that a "manufacturer or distributor shall not deny, restrict, prohibit, or otherwise

[8] HHS's original contract pharmacy guidance was published fourteen years before the ACA. 1996 Guidance, 61 Fed. Reg. at 43551. When Congress revisits a statute that has given rise to a longstanding administrative interpretation and decides not to change it, that decision is "persuasive evidence that the interpretation is the one intended by Congress." *Commodity Futures Trading Comm'n v. Schor,* 478 U.S. 833, 846 (1986) (citation omitted).

interfere with [. . .] delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity." La. Stat. Ann. § 40:2884. Act 1103 states that a drug manufacturer shall not "[d]eny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing." Ark. Code Ann. § 23-92-604(c)(2). Both statutes prevent a drug company from refusing to deliver 340B-priced drugs to contract pharmacies. If anything, Act 358 is even more clearly targeted toward restrictions on "delivery" (i.e., distribution).

Furthermore, contract pharmacies act as agents of covered entities under both Act 358 and Act 1103, and that relationship is not "conspicuously absent here" as AbbVie argues. Pls.' Opp'n 20. Act 358 applies to a contract pharmacy that "is authorized under such contract to receive and dispense 340B drugs *on behalf of* the covered entity…." La. Stat. Ann. § 40:2884 (emphasis added). The Eighth Circuit noted that HHS's contract pharmacy guidance requires an agency relationship between covered entities and contract pharmacies: "[T]he pharmacy becomes an agent of the covered entity with the authorization to 'dispense 340B drugs to patients of the covered entity pursuant to a prescription.'" *PhRMA*, 95 F.4th at 1142 (quoting 1996 Guidance, 61 Fed. Reg. at 43552). Therefore, the agency relationship is mandated by HHS regardless of the implementation of either the Louisiana or Arkansas laws.

AbbVie also tries to distinguish the Arkansas and Louisiana laws by alleging that the Louisiana law does not require the covered entity to maintain title. Pls.' Opp'n 21. Again, HHS's contract pharmacy guidance, not Acts 358 or 1103, requires covered entities to maintain title to 340B discounted drugs held by contract pharmacies. The Eighth Circuit acknowledged that HHS requires covered entities to maintain title: "Covered entities maintain legal title to the 340B drugs." *Id.* (citing 61 Fed. Reg. at 43552); *see also* 2010 Guidance, 75 Fed. Reg. at 10277

("The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price…."). Because a covered entity's maintenance of title is inherent in contract pharmacy arrangements—arrangements that function the same in both the Fifth and Eighth Circuits—Act 358 and Act 1103 are not distinguishable.

A covered entity likewise maintains title under the replenishment model. Under the replenishment model—which is commonly used in all states and approved by HHS—a pharmacy dispenses drugs from its inventory, subsequently determines whether the individual is a patient of the covered entity and therefore eligible to receive 340B drugs and, if so, replenishes the dispensed drug with one purchased by the covered entity at the 340B price. Again, HHS both requires that covered entities maintain title and has endorsed the replenishment model. 2010 Guidance, 75 Fed. Reg. at 10277; Pedley Decl. ¶ 10 ("[HHS] understands that the covered entity is the legal purchaser and authorizes the order" in a replenishment system.).

Replenishment systems are not unique to 340B. *See supra* at 4-5. The Supreme Court endorsed an inventory replenishment system as compliant with a statutory scheme analogous to 340B. The Court analyzed whether hospital purchases through group purchasing organizations are consistent with federal antitrust laws, which, like 340B, permit certain health care providers to purchase discounted drugs for some patients. *Abbott Labs. v. Portland Retail Druggists Ass'n, Inc.*, 425 U.S. 1, 3-4 (1976). The Supreme Court *recommended* a replenishment system in which providers manage their inventories by adjusting inventories at a later date according to general accounting principles. *Id*. at 20-21.

AbbVie's additional attempts to escape the Eighth Circuit's *PhRMA* decision also fail. The severity of penalties under Act 358 and Act 1103 have no bearing on the preemption analysis central to the present case. Just as "Act 1103's penalties are aimed at activity that falls

outside the purview of 340B," so are the Act 358's penalties. *PhRMA*, 95 F.4th at 1145. The Eighth Circuit recognized that Arkansas "is simply deterring pharmaceutical manufacturers from interfering with a covered entity's contract pharmacy arrangements." *Id.* The same is true here. Finally, AbbVie's last-ditch effort to argue that the Eighth Circuit's decision was "simply incorrect," without any meaningful analysis, is meritless. Pls.' Opp'n 22.

II. Act 358 Is Not a Taking and Is a Reasonable Exercise of Louisiana's Police Power

AbbVie's argument that Act 358 constitutes an unconstitutional taking is based on the same flawed premise underlying its preemption argument—that Act 358 governs drug pricing. As explained above, Act 358 does not regulate drug prices but rather regulates drug distribution. Act 358 does not mandate or allow Louisiana to take anything from AbbVie.

Act 358 is not a "*per se* taking" because it does not physically occupy or seize AbbVie's property. Instead, title remains with the covered entity as a required "essential element" of a contract pharmacy arrangement under HHS's guidelines. 2010 Guidance, 75 Fed. Reg. at 10277. Act 358 does not transfer AbbVie's property for a public benefit, nor will it have that effect because Act 358 does not require AbbVie to transfer title of 340B drugs to contract pharmacies. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 528 (2005) (*per se* taking occurs where "an owner … suffer[s] a permanent physical invasion of her property" or a complete deprivation of "*all* economically beneficial us[e]" of her property.") (cleaned up); *Golden Glow Tanning Salon, Inc. v. City of Columbus, Miss.*, 52 F.4th 974, 981 (5th Cir. 2022), *cert. denied*, 143 S. Ct. 1085 (2023) (no *per se* taking because the regulation did not render "the entire property valueless.") (internal quotations omitted). Act 358 is not a physical invasion at all and does not deprive AbbVie of all economically beneficial uses. In fact, 340B drugs make up a "small share of drug company revenues." *See* Healthsperien, *The 340B Drug Pricing Program, A Small Part of the*

Prescription Drug Market, Delivering Large Benefits to Patients and Communities (2024).[9]

Act 358 is also not a regulatory taking under the *Penn Central* factors. *Penn Central Transp. Co. v. N.Y. City*, 438 U.S. 104, 124 (1978). The regulatory takings analysis includes: 1) the economic impact; 2) interference with investment-backed expectations; and 3) the character of the governmental action. Act 358 has no economic impact on AbbVie because 340B prices are set by the 340B statute, not Act 358. Act 358 does not interfere with AbbVie's investment-backed expectations because "no party doing business in a regulated environment" like drug production can expect the regulatory environment "to remain static." *Cmty. Hous. Improvement Program v. City of N.Y.,* 59 F.4th 540, 555 (2d Cir. 2023) *cert. denied sub nom*. *Cmty. Hous. Improvement Program v. City of N.Y.*, 144 S. Ct. 264 (2023). Because HHS authorized contract pharmacy arrangements in 1996, any investment backed expectations since then would include 340B shipments to contract pharmacies. Act 358 was not "enacted solely for the benefit of private parties" and instead furthers "important public interests," *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 485-86 (1987), of protecting Louisiana's safety net health care providers and their patients.

III. Act 358 Is Not Unconstitutionally Vague

AbbVie's reliance on *Carolina Youth Action Project; D.S. by & through Ford v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023), is misplaced. That case dealt with a statute containing numerous undefined terms such as "unnecessarily," "loiter," and "obnoxious," which that court compared to other terms like "annoying" or "indecent" because they are "wholly subjective." *Id.* The *Carolina* court did not analyze the term "interfere," which is not wholly subjective and is "plainly not vague" according to the Fifth Circuit. *Int'l Soc'y for Krishna Consciousness of*

[9] https://www.aha.org/system/files/media/file/2024/03/The-340B-Drug-Pricing-Program.pdf.

Atlanta v. Eaves, 601 F.2d 809, 830-31 (5th Cir. 1979) ("'[U]nreasonably interfere' [is] 'plainly' not vague.") (citation omitted); *see also United States v. Bird*, 124 F.3d 667, 683-84 (5th Cir. 1997) ("[W]e hold that the Act's terms ["interfere with"] are not unconstitutionally vague.").

AbbVie's attempts to distinguish the cases cited by Intervenor-defendant fail. In *International Society for Krishna Consciousness of Atlanta*, the court noted that the vagueness analysis focuses on "fair notice to those to whom the statute is directed" and that "[t]he particular context is all important." *Int'l Soc'y for Krishna Consciousness*, 601 F.2d at 831. The decision did not turn solely on the statute's spatial limitation to airports but emphasized that the statute would "be applied repeatedly by a relatively small number of enforcement officials to a relatively small number of people." *Id.* Act 358 will not be applied against the "public at large in multifarious contexts," *id.*, but rather by a small number of enforcement officials against the small number of manufacturers participating in the 340B program. *Id.*; La. Stat. Ann § 40.2885. In *United States v. Bird*, the court did not cite the statute's spatial restrictions in its reasoning at all. *United States v. Bird*, 124 F.3d at 683-84. The *Bird* court concluded that "in at least the vast majority of cases whether or not the terms of [the statute] apply will be adequately clear; the theoretical possibility that some rare case at the margins of [the statute] might arise where the applicable [sic] of its terms could be unclear does not avail Bird." *Id.* The same is true here.

This Court should reject AbbVie's attempts to classify Act 358 as quasi-criminal. Potential penalties under Act 358 are plainly civil, not criminal, but whether Act 358 is strictly civil or quasi-criminal is of no import. Even if Act 358 were quasi-criminal, it would still pass constitutional muster. One of the most important factors in assessing whether a statutory term is vague is whether the statute hinges on threats to constitutionally protected rights. *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 499 (1982). Unless a statute

proscribes a substantial amount of constitutionally protected conduct, impinges fundamental rights, or employs classifications subject to heightened scrutiny, courts tend to view a challenge to economic regulations with "skepticism due respect for legislative choices," *Levin v. Com. Energy, Inc.*, 560 U.S. 413, 426 (2010), and will only invalidate a statute that is "impermissibly vague in all of its applications." *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122-23 (5th Cir. 1991) (quotations omitted). Act 358's focus is economic, threatens no fundamental rights, and is not impermissibly vague in all of its applications.

Moreover, the vagueness standard is not applied mechanically, and economic regulations, even if quasi-criminal, "are afforded considerable deference in the vagueness analysis because the regulated party may 'have the ability to clarify the meaning of the regulation[s] by its own inquiry, or by resort to an administrative process.'" *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122-23 (5th Cir. 1991) (quoting *Vill. of Hoffman Ests*., 455 U.S. at 498). Considerable deference is due here.

Finally, AbbVie grasps at straws by citing hypothetical situations in which Act 358's interference provision "may apply" or "could theoretically reach." Pls.' Opp'n 34. First, AbbVie's argument that Act 358 may apply to "any" pharmacy fails to acknowledge that the drugs must be dispensed to the patient of a Louisiana covered entity, as LPCA explained in its opening brief. Intervenor-Def.'s Mot. Summ. J. 25, ECF No. 61-1. Second, void for vagueness law does not turn on the theoretical situations AbbVie can "conjure up." *See Int'l Soc. for Krishna Consciousness of Atlanta*, 601 F.2d at 830-31.

CONCLUSION

For the foregoing reasons, the Court should grant LPCA's motion for summary judgment and deny AbbVie's motion for summary judgment.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Intervenor-Defendant's Reply in Support of Its Motion for Summary Judgment was electronically filed with the Clerk of Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

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